

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

REED R. HEIMBECHER
LEGAL DEPARTMENT
ST. JUDE MEDICAL, AF DIVISION, INC.
14901 DEVEAU PLACE
MINNETONKA, MN 55345-2126

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing
(day/month/year)

07 JUL 2008

Applicant's or agent's file reference
OB-050301WO

FOR FURTHER ACTION See paragraphs 1 and 4 below

International application No.
PCT/US 07/89110

International filing date
(day/month/year) 28 December 2007 (28.12.2007)

Applicant ST. JUDE MEDICAL, ATRIAL FIBRILATION DIVISION, INC.

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: +41 22 740 1435

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSIP: 571-272-1774

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 08-050301WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US 07/89110	International filing date (<i>day/month/year</i>) 28 December 2007 (28.12.2007)	(Earliest) Priority Date (<i>day/month/year</i>) 29 December 2006 (29.12.2006)
Applicant ST. JUDE MEDICAL, ATRIAL FIBRILATION DIVISION, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 2 sheets.

☐ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the language, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed.
☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

b. ☐ This international search report has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (see Box No. II).

3. ☐ Unity of Invention is lacking (see Box No. III).

4. With regard to the title,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established by this Authority to read as follows:

5. With regard to the abstract,

- ☒ the text is approved as submitted by the applicant.
☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1 _____
☒ as suggested by the applicant.
☐ as selected by this Authority, because the applicant failed to suggest a figure.
☐ as selected by this Authority, because this figure better characterizes the invention.
- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 07/89110

A. CLASSIFICATION OF SUBJECT MATTER

IPC(B) - A61N 1/00 (2008.04)

USPC - 607/101, 122

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

USPC: 607/101, 122

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched
USPC: 607/101, 122
(text search)

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
PubWEST(PGFB,USPT,USQC,EPAB,JPAB); Google
Search terms: catheter, ablation, slot, fluid, curve, electrode, cardiac, heart, polyvinyl alcohol, expanded polytetrafluoroethylene

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2006/0287650 A1 (CAO, et al.) 21 December 2006 (21.12.2006) Figs. 12, 6-7; para [0011], [0020]-[0071], [0025], [0027], [0053], [0057]-[0058], [0060], [0064]-[0065], [0069], [0072], [0077], [0080]-[0081]	1-21

☐ Further documents are listed in the continuation of Box C.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z" document member of the same patent family

Date of the actual completion of the international search

26 June 2008 (26.06.2008)

Date of mailing of the international search report

07 JUL 2008

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US, Commissioner for Patents

P.O. Box 1450, Alexandria, Virginia 22313-1450

Facsimile No. 571-273-3201

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300

PCT OSP: 571-272-3774

Form PCT/ISA/210 (second sheet) (April 2007)

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To: REED R. HEIMBECHER
LEGAL DEPARTMENT
ST. JUDE MEDICAL, AF DIVISION, INC.
14901 DEVEAU PLACE
MINNETONKA, MN 55345-2126

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 0B-050301WO		Date of mailing (day/month/year) 07 JUL 2008
FOR FURTHER ACTION See paragraph 2 below		
International application No. PCT/US 07/89110	International filing date (day/month/year) 28 December 2007 (28.12.2007)	Priority date (day/month/year) 29 December 2006 (29.12.2006)
International Patent Classification (IPC) or both national classification and IPC IPC(B) - A61N 1/00 (2008.04) USPC - 607/101, 122		
Applicant ST. JUDE MEDICAL, ATRIAL FIBRILATION DIVISION, INC.		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450, Alexandria, Virginia 22313-1450 Facsimile No. 571-273-3201	Date of completion of this opinion 26 June 2008 (26.06.2008)	Authorized officer: Lee W. Young PCT Helpdesk: 571-272-4300 PCT OSP: 571-272-7774
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Form PCT/ISA/237 (cover sheet) (April 2007)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 07/89110

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed.
 - ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the rectification of an obvious mistake authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a)).
3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, this opinion has been established on the basis of:
 - a. type of material
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☐ on paper
 - ☐ in electronic form
 - c. time of filing/furnishing
 - ☐ contained in the international application as filed
 - ☐ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 07/89110

Box No. V	Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1. Statement			
Novelty (N)	Claims	1-21	YES
	Claims	None	NO
Inventive step (IS)	Claims	None	YES
	Claims	1-21	NO
Industrial applicability (IA)	Claims	1-21	YES
	Claims	None	NO
2. Citations and explanations:			
Claims 1-21 lack inventive step under PCT Article 33(3) for being obvious over US 2006/0287650 A1 to Cao et al. (hereinafter "Cao").			
<p>As to claim 1, Cao teaches an ablation catheter for ablating tissue, the ablation catheter comprising:</p> <p>(a) a catheter shaft, said catheter shaft comprising a proximal portion and a distal portion, said distal portion being adapted to be inserted into a body having tissue to be treated and being disposed remotely from said proximal portion, said distal portion comprising a plurality of porthole-shaped openings located on a circumference of the distal portion and being adapted to deliver a conductive medium to the tissue to be ablated, said plurality of porthole-shaped openings arranged along the circumference of the catheter shaft (para [0025], [0064], [0080]-[0081]; Figs. 1, 6-7);</p> <p>(b) a lumen disposed within said distal portion, said lumen adapted to carry the conductive medium (para [0025]); and</p> <p>(c) an electrode disposed within said distal portion of the catheter shaft, said electrode being adapted to supply ablation energy to the conductive medium (para [0025]).</p> <p>Cao does not teach that the plurality of openings are slotted, rather than porthole shaped (i.e., round). However, it would have been obvious to make the openings slotted, because one of skill in the art would have known that openings of any shape would have performed the same function, namely, to deliver a conductive medium to the tissue to be ablated. It further would have been obvious because Cao teaches that the opening may be a single linear slot (para [0057]; Fig. 2), and one of skill in the art would have known that a plurality of openings could take the same shape. Cao further does not teach that each of the plurality of openings spans at least about 25% of the circumference of said distal portion of said catheter shaft. However, Fig. 2 of Cao appears to show the single opening spanning about 25% of the circumference of said distal portion. Accordingly, it would have been obvious that the plurality of openings would also span at least about 25% of the circumference.</p> <p>As to claim 2, Cao teaches that the catheter further comprises a fluid manifold along at least a portion of the catheter (para [0025]).</p> <p>As to claim 3, Cao teaches that the fluid manifold has tubing made of polyvinyl alcohol foam or expanded polytetrafluoroethylene (para [0025], [0069]).</p> <p>As to claim 4, Cao teaches that said distal portion of said catheter shaft comprises at least one curved section (para [0053]; Fig. 1).</p> <p>As to claim 5, Cao teaches that said distal portion of said catheter shaft comprises at least one shape memory wire that is configured to create the at least one curved section (para [0065]).</p> <p>As to claim 6, it would have been obvious that the openings span about 25% of the circumference (see explanation above for claim 1). Cao does not teach that each of said plurality of openings spans about 33% of the circumference of said distal portion of said catheter shaft. However, it would have been obvious that each of said openings would span about 33% of the circumference, because one of skill in the art would have known that a larger opening would have been able to deliver a greater amount of conductive medium to the tissue being ablated, which would increase the ablative power of the catheter, and that it would be desirable to make the openings as large as possible while still maintaining the structural integrity of the catheter.</p> <p>As to claim 7, Cao teaches that said distal portion of said catheter shaft comprises a plurality of curved sections to form a circular shape (para [0053], [0058]; Fig. 2).</p> <p>As to claim 8, Cao teaches a catheter for treating tissue, the ablation catheter comprising a catheter shaft, said catheter shaft comprising a proximal portion and a distal portion, said distal portion being adapted to be inserted into a body having tissue to be treated and being disposed remotely from said proximal portion, said distal portion comprising at least one porthole-shaped opening, with each of said one porthole-shaped opening being located on a circumference of the distal portion, wherein said at least one porthole-shaped opening is arranged along the circumference of the distal portion (para [0025], [0064], [0080]-[0081]; Figs. 1, 6-7). Cao does not teach that the openings are slotted. However, it would have been obvious to one of skill in the art to use slotted openings, for the reasoning given above for claim 1. Cao further does not teach that each opening spans about 1/3 to about 2/3 of the circumference of the distal portion of the catheter shaft. However, it would have been obvious to one of skill in the art that the openings would be of that size, for the same reasoning given above for claim 6.</p>			
(Continued in Supplemental Box)			

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US 07/89110

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

Box V. 2. Citations and Explanations:

As to claim 9, Cao teaches that said distal portion comprises at least one lumen adapted to carry the conductive medium (para [0025]).

As to claim 10, Cao teaches that the catheter further comprises an electrode disposed within said distal portion and a conductive medium manifold running along a portion of said electrode, said conductive medium manifold having a plurality of passageways through which a conductive medium may pass (para [0025], [0064]; Figs. 6-7).

As to claim 11, Cao teaches that the catheter further comprises a lumen extending from said proximal portion to said distal portion, said lumen being adapted to carry a conductive medium from said proximal portion to said distal portion; and a metal electrode mounted within said lumen, wherein said metal electrode is adapted to supply ablative energy to the conductive medium (para [0020], [0025]).

As to claim 12, Cao teaches that said distal portion of said catheter shaft comprises at least one curved section (para [0053]; Fig. 1).

As to claim 13, Cao teaches that said distal portion of said catheter shaft comprises at least one shape memory wire that is configured to create the at least one curved section (para [0065]).

As to claim 14, Cao teaches that the catheter shaft further comprises a second lumen extending along said distal portion, and wherein said shape memory wire is located within said second lumen (para [0027], [0072]).

As to claim 15, Cao teaches that the electrode is coupled with conductive mesh material, and that the mesh material may be made from platinum wire (para [0025], [0060]). Cao further teaches that the electrode lead is connected to an RF generator by an electrical lead that extends through at least a portion of the distal portion of said catheter shaft (para [0052], [0056]). Cao does not teach that the electrode is a platinum flat wire. However, it would have been obvious to one of skill in the art to use a platinum flat wire, because a platinum flat wire would perform the same function as the platinum wire mesh taught by Cao, yet be more durable.

As to claim 16, Cao teaches a method for treating cardiac arrhythmia, said method comprising:

(a) inserting an ablation catheter into a patient having cardiac tissue to be treated ([0011], [0080], [0081]); said ablation catheter comprising:

i. a proximal portion and a distal portion, said distal portion being disposed remotely from said proximal portion, said distal portion comprising a plurality of porthole-shaped openings, wherein said plurality of porthole-shaped openings is adapted to introduce ablative energy to the cardiac tissue to be treated, wherein said plurality of porthole-shaped openings are each located on a circumference of said distal portion (para [0025], [0064], [0080]-[0081]; Figs. 1, 6-7);

ii. an electrode disposed within said distal portion, said electrode having a fluid manifold along at least a portion of said electrode, said electrode adapted to be connected to an ablative energy source (para [0025], [0056]);

wherein the plurality of openings permit the catheter to ablate tissue in both the posterior wall of the left atrium and the pulmonary vein (para [0021]);

(b) placing the ablation catheter along the cardiac tissue to be treated (para [0080]-[0081]); and

(c) applying ablative energy to the ablative catheter to form lesions on the cardiac tissue (para [0080]-[0081]).

Cao does not teach that the openings are slotted. However, it would have been obvious to one of skill in the art to use slotted openings, for the same reasoning given above for claim 1. Cao does not teach that each opening spans between about 90, and about 270, of the circumference of the catheter shaft. However, it would have been obvious to have openings of such size, for the same reasoning given above for claim 6.

As to claim 17, Cao teaches an ablation catheter for ablating tissue, the ablation catheter comprising:

(a) a catheter shaft, said catheter shaft comprising a proximal portion and a distal portion, said distal portion being adapted to be inserted into a body having tissue to be treated, and being disposed remotely from said proximal portion, said distal portion comprising a plurality of porthole-shaped openings located on a circumference of the distal portion, said plurality of porthole-shaped openings arranged along the circumference of the catheter shaft (para [0025], [0064], [0080]-[0081]; Figs. 1, 6-7); and

(b) a metal electrode disposed within said distal portion of the catheter shaft, said electrode being adapted to supply ablative energy through the porthole-shaped openings to the tissue being ablated (para [0020], [0025], [0056]).

Cao does not teach that the openings are slotted. However, it would have been obvious to one of skill in the art to use slotted openings, for the same reasoning given above for claim 1. Cao further does not teach that each of the plurality of openings spans at least about 90 degrees of the circumference of said distal portion of said catheter shaft. However, Fig. 2 of Cao appears to show the single opening spanning about 90 degrees of the circumference of said distal portion.

As to claim 18, Cao teaches that the catheter further comprises a fluid manifold along at least a portion of the metal electrode, and wherein said openings are adapted to deliver conductive fluid to the tissue to be ablated (para [0025]).

As to claim 19, Cao teaches that the fluid manifold has tubing made of a porous polymer (para [0025], [0059]).

As to claim 20, Cao does not teach that the openings span about 33% to about 67% of the circumference of the distal portion. However, it would have been obvious to one of skill in the art to use openings of such size, for the same reasoning given above for claim 6.

(Continued in Supplemental Box)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.
PCT/US 07/89110

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.
Continuation of:

Box V. 2. Citations and Explanations (first Supplemental Box):

As to claim 21, Cao teaches a method for simultaneously ablating tissue that is in at least two different orientations within a body, the method comprising:

- (a) inserting an ablation catheter into a patient having tissue to be ablated ([0011], [0080]-[0081]); said ablation catheter comprising:
 - i. a proximal portion and a distal portion, said distal portion being disposed remotely from said proximal portion, said distal portion comprising a plurality of porthole-shaped openings, wherein said plurality of porthole-shaped openings are adapted to introduce ablative energy to the cardiac tissue to be treated, wherein said plurality of porthole-shaped openings are located on a circumference of the distal portion (para [0025], [0064], [0080]-[0081]; Figs. 1, 6-7); and
 - ii. an electrode disposed within said distal portion, said electrode adapted to be connected to an ablative energy source (para [0025], [0058]);
 - (b) placing the ablation catheter along the tissue to be treated (para [0077], [0080]-[0081]); and
 - (c) applying ablative energy to the ablation catheter to form lesions simultaneously on tissue that is in at least two different orientations (para [0077], [0080]-[0081]).
- Cao does not teach that the openings are slotted. However, it would have been obvious to one of skill in the art to use slotted openings, for the same reasoning given above for claim 1. Cao further does not teach that each of the plurality of openings spans about 33% to about 67% of the circumference of said distal portion of said catheter shaft. However, it would have been obvious to one of skill in the art to use openings of such size, for the same reasoning given above for claim 6.

Claims 1-21 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.